Eon Labs
The Pharmacy Drug Company

Eon Labs Manufacturing, Inc.
227-15 N. Conduit Avenue
Laurelton, NY 11413
Telephone 718 276-8600
Fax 718 949-3120

May 11, 1999

Dockets Management Branch (HFD-305)
Center for Drug Evaluation and Research
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

4328 '99 MAY 19 P4:17

## -REQUEST FOR A HEARING-

***Re:*** ***Docket No 77N-0240***
***Reference No: Desi 1786***

***Nitroglycerin Sustained Release Capsules, 2.5 mg, ANDA 87-975;***
***Nitroglycerin Sustained Release Capsules, 6.5 mg, ANDA 87-976***
***Nitroglycerin Sustained Release Capsules, 9 mg; ANDA 88-509***

Dear Ms. Catchings;

Eon Labs Manufacturing, Inc. (formerly Vitarine Co.) manufacturers and distributes Nitroglycerin Sustained Release Capsules, 2.5 mg, 6.5 mg, and 9 mg in accordance with the test methods and specifications approved in the above referenced ANDA's. A recent Federal Register Notice dated April 20, 1999, announced FDA's intention to withdraw single-entity coronary vasodilators containing nitroglycerin from the market due to lack of substantial bioequivalence and bioavailability data submitted by an applicant. The FDA is providing an opportunity for a hearing before implementing this action.

In response to the FR notice, Eon Labs is **requesting a hearing** for the reason that in September 16, 1982, Eon Labs Manufacturing, Inc. did in fact submit bioavailabiltiy data for the 6.5 mg dosage strength. Data from this study was used to support both the 2.5 mg and 9 mg dosage strengths. The analytical method used for the study was the DPG method which was considered the only procedure at that time that could measure bioavailability parameters.

Within the requirements of the FR notice, Eon Labs will submit to the agency supporting data by June 21, 1999, in preparation for the hearing. Until that time, fell free to call me at (718) 276-8607 x 330 if additional information is required. Thank you for your consideration to this matter.

Regards,

Sadie M. Ciganek
Vice President Regulatory Affairs

77N-0240

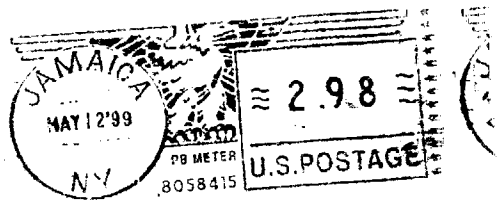
HEL 40

Eon Labs
A Health Care Company

Eon Labs Manufacturing, Inc.
227-15 N. Conduit Avenue
Laurelton, New York 11413

CERTIFIED

Z 058 074 167




MAIL

Dockets Management Branch (HFD-305)
Center for Drug Evaluation and Research
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

20705/2820